



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Estela Raychaudhuri  
President/CEO  
InBios International, Inc.  
562 1<sup>ST</sup> Avenue South  
Suite 600  
Seattle, Washington 98104

JUL 26 2000

Re: K001092  
Trade Name: Generic Blood Glucose Test Strip  
Regulatory Class: II  
Product Code: NBW, CGA  
Dated: June 22, 2000  
Received: June 28, 2000

Dear Ms. Raychaudhuri:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

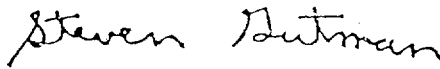
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, flowing style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

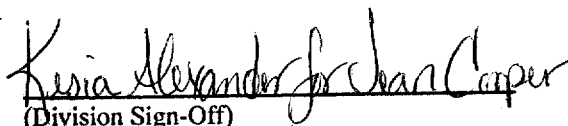
Enclosure

510(k) NUMBER (IF KNOWN): K001092

DEVICE NAME: GENERIC BLOOD GLUCOSE TEST STRIP

INDICATION FOR USE:

Generic Blood Glucose Test Strips are a component of an in vitro diagnostic test system used for the quantitative measurement of glucose in capillary whole blood. This product is intended to be used at home by diabetics. The test strips are designed to be used with the One Touch® Blood Glucose Meters.



(Division Sign-Off)

Division of Clinical Laboratory Devices

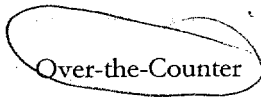
510(k) Number K001092

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation

Prescription Use

or

  
Over-the-Counter